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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,040	11/15/2000	Paul J. Carter	11669.185USD3	5212

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,040

Applicant(s)

CARTER, PAUL J.

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,29 and 38-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-42 is/are allowed.
- 6) ☒ Claim(s) 25,29, 38-39 and 44-48 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/14/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24, 26-28 and 30-37 are cancelled.
Claims 25 and 40 are presently amended.
Claims 44-48 have been added.
2. Claims 25, 29 and 38-48 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Withdrawn Objections/Rejections

5. The objection to the specification as containing the incorrect citation for Glennie et al is withdrawn in view of the amendments filed 2/1/2006.
6. The rejection of claims 25, 29 and 38-43 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation "first and second Fab', each first and second F(ab') in claim 25 and "first and second F(ab'), wherein each first and second Fab" in claim 40 is withdrawn in view of the amendments to the claims.

Response to Arguments

7. The rejection of claims 25, 38 and applied to newly added claims 44 and 46-48 under 35 U.S.C. 102(b) as being anticipated by Bodmer et al (WO 89/01974, 3/9/1989) is maintained.

Art Unit: 1643

The response filed 2/1/2006 states that claim 25 is now directed to a F(ab')₂, wherein each Fab' comprises a CH1 domain fused to an amino acid sequence of about 1 to 10 amino acids comprising a C-terminal amino acid sequence of Cys-X-X, wherein Ala, Arg, Pro or Asp and Bodmer does not teach or suggest such a F(ab')₂. This has been fully considered but is not found persuasive. The art of Bodmer still reads on the claims, which only require that the amino acid sequence be about 1-10 amino acids and comprise a C terminal amino acid sequence Cys-X-X. The claims still do not require the Cys-X-X or Cys-Pro-Pro tripeptide to be fused to the CH1 domain and thus, the Cys-Pro-Pro located C-terminally in the human IgG1 hinge sequence (Fig. 1) still reads on the claims. Further, as evidenced by the specification at pg. 12, lines 6-7, applicant acknowledges that the hinge region of human IgG1 is about 10 amino acids and contains the Cys-Pro-Pro sequence, which was known in the prior art (see pg. 11, lines 27-31).

Newly added claims 44 and 46-48 are drafted in the product-by-process format. The reference does not describe the production of the molecule using the methods identical to that is recited in the claims. However, the recitation of a process limitation in the claims is not viewed as positively limiting the claimed product absent a showing that the process of making recited in the claims imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is placed upon the applicant to establish a patentable distinction between the claimed and references products. See MPEP 2113. Further, Bodmer et al teach that the

Art Unit: 1643

altered antibody molecule (AAM) may be attached via a free thiol to a heterologous molecule including the detectable radiolabel, ^{99m}Tc or the toxin, ricin (see pp. 5-6 and 7). Thus, the art of Bodmer et al reads upon newly added claims 44 and 46-48.

For these reasons and those already of record, the rejection is maintained.

New Grounds of Rejections

8. Claims 25, 29, 38-39 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 25, 29 and 38-39 are indefinite in the recitation "wherein the amino acid sequence of about 1 to 10 amino acids comprises a C terminal amino acid sequence Cys-X-X, wherein X is Ala, Arg, Pro or Asp" in claim 25. The sequence defined by the formula Cys-X-X is minimally 3 amino acids in length, which raises a question as to the metes and bounds of the claimed invention where the CH1 domain is fused to an amino acid sequence that is about 1 or about 2 amino acids.

b. Claims 44-48 are indefinite in the recitation "A composition produced by the process" in claims 44 because the claims do not clearly set forth or define what the composition is. Are the claims drawn to a monospecific F(ab')_2 , a monospecific F(ab')_2 conjugated to a heterologous molecule, a Fab' conjugated to a heterologous molecule or is some other "composition" contemplated? As

Art Unit: 1643

written, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed composition.

9. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 2/1/2006 has introduced NEW MATTER into the claims. Newly added claim 47 recites that the Fab' is covalently bonded via a free thiol to a heterologous molecule that is a detectable label, cytotoxic drug, toxin or solid support. The response pointed to page 11, lines 24-35, page 14, lines 7-25 and page 35, lines 9-23 for support for newly added claims 44-48, however, there is insufficient written support for the Fab' covalently bonded via a free thiol to a cytotoxic drug or a toxin. The as filed specification as pointed to by applicant only discloses conjugation to a fluorescent probe, radionuclide and a solid support via the free thiol (see pg. 35). Newly added claim 47 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in newly added claim 47, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in newly added claim 47 in the specification or

Art Unit: 1643

claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

10. Claims 40-42 appear to be free of the prior art. Claim 43 is objected to as being dependent upon a rejected base claim.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry

Art Unit: 1643

Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



SHEELA HUFF
PRIMARY EXAMINER